

- 11 -

CLAIM

1. A novel crystalline polymorph Form-VI of 2-methyl-4-(4-methyl-1-piperazinyl)-10H-thieno[2,3-b][1,5] benzodiazepine (Olanzapine).

2. The crystalline polymorph Form-VI of Olanzapine of claim 1 having X-ray powder diffraction pattern with characteristic d-values (in Å) percentage (in %) as shown in the following table.

d-values	Intensity (%)
10.2972	35
8.5646	6
7.6618	22
7.4935	21
7.3691	21
6.6317	25
6.5246	29
6.2320	87
5.7713	7
5.7121	9
5.3042	20
5.2174	6
4.9733	34
4.8335	7
4.7614	5
4.7162	8
4.6284	27
4.4802	13
4.3795	54
4.3163	77
4.2874	100
4.2308	21
4.1297	34
4.0958	34
4.0117	17
3.8275	24
3.7263	13
3.6509	17
3.5311	6
3.3141	29
3.2782	18
3.1207	17
3.0035	5

- 12 -

d-values	Intensity (%)
2.8824	5
2.8099	8
2.8014	6
2.0562	6

- 5      3.      The crystalline polymorph Form-VI of Olanzapine of claim 2, having an X-ray powder diffraction pattern as depicted in Figure (1).
4.      The crystalline polymorph Form-VI of Olanzapine of claim 1, having differential scanning calorimetry thermogram which exhibits a characteristic endo peak around 196°C.
- 10     5.      The crystalline polymorph Form-1 of Olanzapine of claim 4, having a differential scanning calorimetry thermogram as depicted in Figure (2).
6.      The crystalline polymorph Form-VI of Olanzapine of claim 1, having identified characteristic peaks around 3217 cm<sup>-1</sup>, 2933 cm<sup>-1</sup>, 1592 cm<sup>-1</sup>, 1561 cm<sup>-1</sup>, 1468 cm<sup>-1</sup>, 1369 cm<sup>-1</sup>, 1218 cm<sup>-1</sup>, 1143 cm<sup>-1</sup>, 1007 cm<sup>-1</sup>, 964 cm<sup>-1</sup>, 751 cm<sup>-1</sup> and 674 cm<sup>-1</sup> in the
- 15     Infra red Spectrum.
7.      The crystalline polymorph Form-VI of Olanzapine of claim 6, having an Infrared spectrum as depicted in Figure (3).
8.      A process for the preparation of novel crystalline polymorph Form-VI of 2-methyl-4-(4-methyl-1-piperazinyl)-10H-thieno [2, 3-b] [1,5 ]benzodiazepine
- 20     (Olanzapine), which comprises;
- (i)      stirring polymorph Form-I of Olanzapine in a C<sub>1</sub>-C<sub>6</sub> alkanol at a temperature of 0 to 40°C for 30 minutes to 10 hours;
- (ii)     isolating the obtained solid form step (i) by conventional methods; and
- 25     (iii)     drying the compound of step (ii) at a temperature of 40 to 100°C to afford the desired crystalline polymorph Form-VI of Olanzapine.
9.      The process as claimed in claim 8, of step (i), wherein the said alcohol is n-butanol or tert-butanol.
10.     A composition comprising novel crystalline Form VI of 2-methyl-4-
- 30     (4-methyl-1-piperazinyl)-10H-thieno [2,3-b] [1,5] benzodiazepine according to any one of claims 1 to 7 and pharmaceutically acceptable carrier, diluent, excipient, additive, filler, lubricant, binder, stabilizer, solvent or solvate.

- 13 -

11. The composition according to claim 10, in the form of a tablet, capsule, lozenge, powder, syrup, solution, suspension, ointment, or dragee.

12. The composition according to any one of claims 10 or 11, for the treatment of a disorder of the central nervous system.

5 13. A method for treating a disorder of the central nervous system comprising administering an effective amount of crystalline Form VI of 2-methyl-4-(4-methyl-1-piperazinyl)-10H-thieno [2,3-b] [1,5] benzodiazepine according to any one of claims 1-7 and a pharmaceutically acceptable carrier, diluent, excipient, additive, filler, lubricant, binder, stabilizer, solvent or solvate to a patient in need thereof.

10 14. A medicine for the treatment of a disorder of the central nervous system comprising an effective amount of crystalline Form VI of 2-methyl-4-(4-methyl-1-piperazinyl)-10H-thieno [2,3-b] [1,5] benzodiazepine according to any one of claims 1-7.

15 15. Use of crystalline Form VI of 2-methyl-4-(4-methyl-1-piperazinyl)-10H-thieno [2,3-b] [1,5] benzodiazepine according to any one of claims 1-7 for the preparation of a medicament for the treatment of a disorder of the central nervous system.